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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/746,919	12/22/2000	Howard Marcellus Johnson	5600-0001.37	2742

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EXAMINER	
SEHARASEYON, JEGATHEESAN	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 07/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.	Applicant(s)	
09/746,919	JOHNSON ET AL.	
Examiner	**Art Unit**	
Jegatheesan Seharaseyon	1647	

Office Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *55-59,66-71,96 and 97* is/are pending in the application.

4a) Of the above claim(s) *55-59 and 96* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *66-71 and 97* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This office action is response to Applicant's election of Group II, claims 66-71 and 97, are drawn a method of inhibiting viral replication limited to SEQ ID NO: 2. Election was made with traverse in Paper No. 9 (5/16/02). The traversal is on the ground(s) that the search of all sequences would not impose a serious burden on the Office. This is not found to be persuasive because the different polypeptide sequences described are fragments of SEQ ID NO: 2 (pages 16-17) and do not share common core sequence and thus do not share substantial structural feature or function. Contrary to the assertion made by the Applicant, the Official Gazette notification is applicable both to the protein as well as nucleotide sequences. Furthermore, Applicant notes that the seven claimed sequences are presented as a Markush group. However, since they do not share a substantial feature they do not belong to a Markush group. Finally, the various sequence fragments are considered separate inventions. Thus, if a single SEQ ID NO: is found allowable, other sequences will not be further considered for examination purposes. Therefore, the restriction requirement is deemed proper and made FINAL.

Drawings

2. The drawing has been approved by the draftsperson.

Specification

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 112

4.The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 66 and 97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4a. Claims 66 and 97 are rejected as being vague and indefinite because of the recitation of the phrase "at least about". This language is vague and indefinite since it makes the dosage rather imprecise (see MPEP2173.05(b)A). The court has held that claims reciting "at least about" were invalid for indefiniteness where there was close prior art and there was nothing in the specification, prosecution history, or the prior art to provide any indication as to what range of specific activity is covered by the term "about." Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d1200, 18 USPQ2d 1016 (Fed. Cir. 1991). Claims 67-70 are rejected insofar as they depend on claim 66.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5a. Claims 66-71 and 97 rejected under 35 U.S.C. 103(a) as being unpatentable over Imakawa et al. (Nature 330: 377-79,1987) in view of Imakawa et al. (J. Cell Biol. 105 (4, part 2): 11A, abst. No. 49, 1987) and Cummins (U. S. Patent No. 5,019,382).

Imakawa (Nature) evidences that means for purifying oTP-1 (ovineIFN-tau) to a high degreee of purity and a cDNA encoding a mature oTP-1 polypeptide having identical sequence of instant SEQ ID NO: 2 were known in the art (Fig. 2). The reference observes that the sequence of oTP-1 and the bovine homolog, bTP-1 exhibit a significant degree of homology to the sequences of a variety of mammalian alpha interferons. It notes that IFNs have a variety of valuable biological properties and teaches that oTP-1 may exhibit such properties including antiviral activity (page 378). However, the Nature paper does not affirmatively teach that oTP-1 does in fact exhibit such properties and does not exemplify the treatment of cells with oTP-1 protein.

The Imakawa (JCB) reference is a printed meeting abstract. Although brief, it affirmatively states that "we have also shown that oTP-1 has the antiviral and antiproliferative properties of an IFN."

Cummins is relied upon as it describes that the antiviral properties of alpha IFNs were well known in the art. In particular, it observes that an IFN, by definition, must exhibit 'virus nonspecific, antiviral activity at least in homologous cells..."(column 1, lines 23-27). It teaches that among the viral infections that are susceptible to IFN

therapy are AIDS caused by HIV a RNA virus, and cold sores caused HSV-I by a DNA virus (column 4, line 65- column 5, line24).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to treat cells infected with any RNA virus, such as HIV, or any DNA virus, such as HSV-I, with oTP-1 as described by Imakawa (Nature), because Cummins teaches that infections caused by any such viruses can be effectively treated (inhibit viral replication) with IFNs; Imakawa (Nature) teaches that oTP-1 has structural properties of an alpha IFN: and because Imakawa (JCB) teaches that the IFN-like antiviral properties of oTP-1 have been confirmed experimentally. Although, the dosages recited in the invention have not been taught by the art, knowing the similarity to other IFNs one skilled in the art would have tried various dosages to optimize the doses to inhibit viral replication. Thus the claimed invention would have been *prima facie* obvious as a whole at the time it was made, especially in the absence of evidence to the contrary. Therefore, the instant invention is obvious over Imakawa et al. (Nature 330: 377-79,1987) in view of Imakawa et al. (J.Cell Biol. 105 (4, part 2): 11A, abst. No. 49, 1987) and Cummins (U. S. Patent No. 5,019,382). Claim 70 is rejected insofar as it depends on claim 69.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6a. Claims 66-71 and 97 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 5,942,223.

The instant invention is directed to a method of inhibiting viral replication, comprising contacting cells infected with a virus ovine interferon-tau at dosages to inhibit viral replication within said cells.

U.S. Patent No. 5,942,223 claims a method of inhibiting viral replication, comprising contacting cells infected with a virus ovine interferon-tau at dosages to inhibit viral replication within said cells. The broad claims generically read on the instant invention, though the patent does not explicitly recite the use of various doses of ovine interferon-tau to inhibit the viral replication within said cells.

It would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made, to modify the methods claimed in the patent to optimize

the dose to inhibit viral replication in cells. This is because the allowed patent contemplates doses ($5x10^4$-$5x10^8$) that are greater than those which can generally be utilized for other interferon (column 27 lines 21-29). Furthermore, SEQ ID NO: 2 encodes for ovine interferon-tau. Thus, claims 66-71 and 97 of the instant application are obvious over claims 1-8 of U.S. Patent No: 5,942,223.

7. No claims are allowable.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

js
July 23, 2002

Gary L. Kunz
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